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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/673,168 | 11/28/2000 | Roald Skurtveit | NIDN-10370 | 2221 |

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AMERSHAM BIOSCIENCES
PATENT DEPARTMENT
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| EXAMINER |
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SHARAREH, SHAHNAM J

| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 06/04/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,168

Applicant(s)

SKURTVEIT ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed on March 04, 2003 has been entered. Applicant's election with traverse of phosphatidylserine-stabilized perfluorobutane and sodium dodecyl sulphate in Paper No. 9B has been acknowledged. The search is directed to the elected species and their respective subgenus of phospholipids and alkyl sulphates. Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 1, 5 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recitation of "an initially coalescence-resisting surface membrane,..." renders the scope of the claim ambiguous. It is not clear what compounds encompass "an initially coalescence-resisting surface membrane." Applicant's argument with respect to this rejection is not persuasive. Applicant argues that the instant application defines this term by reference to WO-A-8002365. Applicants are reminded that the test under 35 USC 112 is not whether another publication provides an example of the term at issue; rather, whether one of ordinary skill in the art can reasonably ascertain the scope of the claim by clearly defining the metes and bounds of its limitations. Here, the application does not incorporate WO-A-8002365 in its entirety, nor does the specification specify the meaning of such limitation.

Furthermore, the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). No such declaration is provided here. Therefore, the claim stand rejected.

Double Patenting

3. Claims 1-20, 23-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,375,931. Applicant argues that the US 6,375,931 does not suggest that its claimed material can be co-administered as a separate component in order to promote microbubble growth by destabilizing the microbubble dispersion.

4. This argument is not persuasive, because the instant claims appear to be drafted in the form of product-by-process claims. Accordingly, product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113.) "Even though product - by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in

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the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus, the argument that the instant material can be co-administered separately does not render the instant products patentably distinct.

As reasoned in previous Office Action, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the instantly claimed invention, because all the pending claims use the same diffusible components thus providing the similar effects as of the diffusible components of the patented claims. Therefore, claims stand rejected.

Claim Rejections - 35 USC § 102

5. Claims 1-13, 15-19, are rejected under 35 U.S.C. 102(e) as being anticipated by Unger US Patent 5,846,517 (Unger I).

6. Applicant's arguments have been fully considered but are not found persuasive. Applicant argues that Unger I does not disclose administration of destabilizing substances to promote controlled growth of microbubbles to effect their temporary retention in the tissue microvasculature.

7. First, with respect to claims 1-16 Examiner replies that such claims are product claims. Unger teaches all elements of such product claims. Namely, Unger uses compositions containing polyethylene glycol and sodium lauryl sulfate (col 27-29). Thus, Unger teaches the use of instantly claimed destabilizing substances set forth in claim 12. subsequently, Unger is anticipating all limitations of the instant product claims.

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8. With respect to product claims 17-20, 23-25, Unger discloses process steps of co administering compositions having all elements of the instant claims. Thus, compositions of Unger are inherently capable of the growth and retention within the tissue microvasculature of interest when subject to ultrasound energy. Applicant's methodologies does not exclude process steps of Unger. (abstract; col 49-line 55, col 50-line67; examples 1-4; col 55, lines 1-30). Therefore, Unger's methods anticipates the limitations of the instant claims. Accordingly, Unger anticipates the limitations of the instant claims.

9. Claims 1-12, 15-18, ~~23~~²⁴-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger US Patent 5,733,572 (Unger II).

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that the compositions of Unger II are adapted for therapeutic use not ultrasound contrast agents.

In response Examiner states that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Unger provides for all elemental limitations of the instant claims. Thus, it is anticipatory for the reasons of record.

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10. Claims 1-20, 23-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Ostensen et al US Patent 6,375,931 (Ostensen).

Applicant's arguments are not found persuasive. Applicant argues that Ostenson's substances may not be separately administered. In response, Examiner states that Ostenson's discloses same components as instantly claimed. Further Ostenson's components are separately packaged. Therefore, the meet all the limitations of the instant claims. The components of Ostenson inherently possess all characteristics of the instant components. Thus, claims stand rejected for the reasons of record.

Claim Rejections - 35 USC § 103

Claims 1-20, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger II.

In response to applicant's argument that Unger does not use the claimed material as a separately administrable substance, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Here, Unger teaches all components and method steps instantly claimed. Unger only fails to use adenosine as a vasodilator, however, as reasoned in previous Office Action, any cardiac drug may be used in combination with Unger's compositions for their own intended clinical end point. Moreover, Applicant has not provided any

evidence showing that the components of Unger is indeed not capable of being administered separately. Thus, the claims stand rejected for the reasons of record.

Conclusion

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned

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are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss

June 1, 2003


RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200